DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2350
Boston, MA 02203

Northeast Division of Survey & Certification

CENTERS FOR MEDICARE & MEDICAID SERVICES

IMPORTANT NOTICE – ACTION NECESSARY

November 14, 2018

Via facsimile to (203) 384-3155.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

Alexander Finkelstein, M.D.
Laboratory Director
Bridgeport Hospital Laboratory
267 Grant Street
Bridgeport, CT 06610

CLIA number: 07D0099572

RE: IMPOSITION OF SANCTIONS – CONDITIONS OUT

Dear Dr. Finkelstein:

The Bridgeport Hospital Laboratory was notified by our letter dated October 19, 2018, of proposed sanctions against the laboratory's CLIA certificate based on the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the surveys completed on July 20, 2018 and September 13, 2018. The laboratory was given ten days from the date of the October 19, 2018, letter to submit information or written evidence as to why these sanctions should not be imposed.

Your laboratory responded with a submission received on October 29, 2018. The submission was in the form of an allegation of compliance (AOC) and evidence of correction.

We have carefully reviewed the entire October 29, 2018, submission and determined that your laboratory's AOC is not credible and evidence of correction is not acceptable. The evidence submitted shows that the laboratory continues to be out of compliance with CLIA Condition-level requirements as cited during the July 20, 2018 and September 13, 2018 surveys.

As you were advised a credible AOC, as defined by the CLIA requirements at 42 C.F.R. § 493.2, is a statement or document that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
3) Indicates resolution of the problem.

It is important to note that for it to be credible, the AOC must be complete and address each of the deficiencies. For each deficiency, the AOC must include a corrective action date that is realistic in terms of

the action being accomplished between the date of the survey and the planned date of completion. In addition, the AOC must contain information that indicates resolution of the problems.

For your information, the following details by deficiency tag (D-tag) why Bridgeport Hospital Laboratory's October 29, 2018, submission does not constitute a credible AOC and acceptable evidence of correction.

- Missing the records and documents requested to show correction of the deficiencies cited for D5411A and D5473 #1.

- Failed to send one month of completed records after cytology testing resumed to show correction of the following deficiencies cited: D3031, D5032, D5203, D5429A, D5429B, D5473 #2, D5791, D6076, D6079, D6094, and D6102.

- D3031: Missing the completed form titled STAIN QUALITY CONTROL/FILING OF SLIDES FORBUCCAL SMEARS (PAP STAIN) to document the slide retention of the buccal smears used to evaluate the quality and stain characteristics of the Papanicolaou stain.

- D5032: The Condition of Cytology is not lifted. Missing the records requested under D5203, D5411A, D5429A, D5429B, and D5473.

- D5203: Missing the completed form titled STAIN QUALITY CONTROL/FILING OF SLIDES FOR METHYLENE BLUE STAINING FOR EFFUSIONS to document the retention of the slides used to assess specimens with a high potential for cross contamination.

- D5411A: Missing SurePath morphology training records for Technical Supervisor #4.

- D5429A: Missing the completed form titled SHANDON CYTOSPIN 4 MAINTENANCE LOG to document the maintenance performed.

- D5429B: Missing the completed forms titled ROTINA 380 NON-GYN CENTRIFUGE MAINTENANCE LOG and ROTINA 380 GYN PROCESESSING CENTRIFUGE MAINTENANCE LOG to document the maintenance performed for each centrifuge.

- D5473: #1. Missing the completed form titled STAIN QUALITY CONTROL/FILING OF SLIDES FOR FNA CART (RAPID H&E) to document the stain assessment of the rapid Hematoxylin and Eosin stain used for fine needle aspirations, each day of use. #2. Missing the completed form titled STAIN QUALITY CONTROL/FILING OF SLIDES HAND STAINING OF HIGHLY CELLULAR EFFUSIONS (PAP) to document the stain assessment of the manual Papanicolaou stain used for non-gynecologic specimens, each day of use.

- D5791: Missing records requested under D5411A, D5429A, D5429B, and D5473.

- D6076: The Condition of Laboratory Director is not lifted. Missing the records requested under D6079, D6094 and D6102.

- D6079: Missing the records requested under D3031, D5203, D5429A, D5429B, and D5473.
- D6094: Missing the records requested under D5791.
- D6102: Missing the records requested under D5411A.

IMPOSED SANCTIONS

Accordingly, as the laboratory has failed to meet all CLIA Conditions and based on the failure of the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the surveys completed on July 20, 2018 and September 13, 2018, we are taking action to impose sanctions against Bridgeport Hospital Laboratory's CLIA certificate as proposed in our October 19, 2018 letter, with effective dates as follows:

• 42 U.S.C. § 263a(i)(3), 42 C.F.R. §§ 493.1806, 493.1840(a)(3) and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate effective January 14, 2019. The laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.

• 42 C.F.R. §§ 493.1806(c)(3), 493.1810(c)(2)(ii), 493.1810(d) and 493.1834 – Alternative Sanction: **Civil Money Penalty (CMP)** in the amount of $3,000 per day for each day of non-compliance effective November 29, 2018. If the laboratory requests a hearing, the civil money penalty amount will not be collected until after the hearing decision is rendered. The $3,000/day will begin to accrue on November 29, 2018, and will continue to accrue until it can be verified that the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is revoked.

• 42 C.F.R. §§ 493.1806(c)(1), 493.1832, 493.1844(d)(1) and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective November 29, 2018. The laboratory is directed to submit to this office within ten calendar days from the date of the imposition notice a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services since July 20, 2018. This list may be used to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory.

• 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842 and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for any laboratory services performed on or after November 29, 2018. This sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), the laboratory's approval to receive payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for any laboratory services performed on or after November 29, 2018. *See* 42 C.F.R. § 440.2(b).

Appeal Rights

If the Bridgeport Hospital Laboratory believes this determination to impose these actions against its CLIA certificate is not correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A request for hearing must be filed **electronically** no later than **sixty (60) calendar days** after the date this letter is received (see 42 C.F.R. § 493.1844(f), 493.1844(g) and 493.1834(e)(2)(i)). You should file your request for an appeal (accompanied by a copy of this letter) to the Department Appeals Board Electronic Filing System website (DAB E-file) at https://dab.efile.hhs.gov. Please note: all documents must be submitted in Portable Document Format ("pdf:"). You are **required** to e-file your appeal request unless you do not have access to a computer or internet service. In such circumstances, you may file in writing, but must provide an explanation as to why you cannot file submissions electronically and request a waiver from e-filing in the mailed copy of your request for a hearing. Written request for appeals must also be filed no later than sixty (60) calendar days after the date this letter is received, and must be submitted to the following address:

Department of Health and Human Services
Departmental Appeals Board, MS 6132
Civil Remedies Division
330 Independence Ave, SW
Cohen Building, Room G-644
Washington, D.C. 20201

A copy of the hearing request should be sent to:

Daniel M. Kristola
Branch Manager
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room-2350
Boston, MA 02203

Reduction of CMP

Pursuant to 42 C.F.R. § 493.1834(e)(2)(iii), if the laboratory waives its right to a hearing, the amount of the CMP may be reduced by 35 percent (35%). If you would like to waive your right to a hearing regarding the imposition of any CMP, you must do so by submitting your written notice of waiver to the following address within sixty (60) calendar days from the date of receipt of this notice:

Daniel M. Kristola, Branch Manager
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room-2350
Boston, MA 02203

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be

presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** ***See*** 42 C.F.R. § 493.643(d)(2).

Please be advised that the determination as to which alternative sanction or sanctions to impose, including the amount of the CMP impose per day or per violation, is not subject to appeal. ***See*** 42 C.F.R. § 493.1844(c)(4).

If a timely request for hearing is filed, i.e., by January 14, 2019, CMS does not collect the CMP or revoke any type of CLIA certificate until after an ALJ hearing that upholds CMS' sanction determination. However, the Directed Portion of a Plan of Correction and cancellation of all Medicare and Medicaid payments are effective regardless of whether a hearing is requested. ***See*** 42 C.F.R. §§ 493.1844(d)(1)-(3) and 493.1844(h)(2). Please be advised that failure to comply with an alternative sanction is independent basis for suspension, limitation or revocation of any type of CLIA certificate.

The laboratory is reminded that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

When a laboratory's CLIA certificate is revoked, it is required to cease all patient laboratory testing, including waived and provider performed microscopy testing and regardless of whether or not the laboratory charges for the testing. Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions. If the sanctions become effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. Pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by posting the information on the Survey & Certification website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices.html.

If you have any questions, please contact Dina Caloggero at (617) 565-1286 or via email: (dina.caloggero@cms.hhs.gov) or Bethzaida Rodriguez at (617) 565-2146 or via email: (Bethzaida.Rodriguez@cms.hhs.gov).

Sincerely,

For

Daniel M. Kristola
Branch Manager
Certification and Enforcement Branch

Cc: Barbara Cass, Connecticut SSA
Cheryl Wiseman, ASCT
Karen Dyer, CMS Central Office, Baltimore, MD